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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/708,306	11/07/2000	Li-Wei Hsu	205032000400	1255

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EXAMINER	
GABEL, GAILENE	
ART UNIT	**PAPER NUMBER**
1641	9

DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/708,306	HSU ET AL.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-20 and 25-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-20 and 25-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group 1, claims 14-20 and 25-29, without traverse, filed 1/16/03 in Paper No. 8 is acknowledged and has been entered. Claims 21-24 have been cancelled. Claims 30 and 31 have been added. Accordingly, claims 14-20 and 25-31 are pending and are under examination.

Rejections Withdrawn

Claim Rejections - 35 USC § 112

2. The rejections of claims 1-13 are now moot, in light of Applicant's cancellation of the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily

published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 14, 15, 17, 19, 20, and 25-27are rejected under 35 U.S.C. 102(e) as being anticipated by Burmer (US 6,087,103).

Burmer discloses a method and kit to screen a plant extract for compounds (ligands), i.e. small organic molecules, that bind selectively to a target protein wherein a crude plant is fractionated (separated by gradient centrifugation) to obtain fractions, i.e. pooled, according to size, molecular, weight, etc. (see column 8, lines 12-65 and column 15, lines 8-24). The method is used to screen and detect for binding of a labeled target to any of the compounds extracted from the plant. The fractions containing the compounds each have a different location (ligand address) that corresponds to a tag having a known address identified by reference to a matrix on a solid support upon which the compounds are incorporated into, a well on a microtiter plate and a corresponding location on a membrane, i.e. plastic microtiter plate (see column 11, lines 16-64). The compound libraries are arrayed spatially in the matrix (see column 1, line 61 to column 2, line 26, column 3, lines 39-42, and column 4, lines 37-42). The compounds and target are contacted, incubated, washed with a buffer to remove unbound components, then detected for any complexes comprising the compound and labeled target protein, i.e. having a detectable moiety (see column 3, lines 62-67 and column 14, lines 19-24). Useful labels for the method and kit include biotin (see column 2, lines 14-17 and column 5, lines 11-23). Burmer discloses that the

screening method finds use in pharmaceutical drug discovery and recovery for the development of lead compounds (see column 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 16, 29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burmer (US 6,087,103) in view of Baek et al. (Agricultural Chemistry and Biotechnology, April 1998 (Abstract)) or Verma et al. (Journal of Medicinal and Aromatic Plant Sciences, September 1997).

Burmer discloses a method and kit to screen a plant extract for compounds (ligands), i.e. small organic molecules, that bind selectively to a target protein wherein a

crude plant is fractionated (separated by gradient centrifugation) to obtain fractions, i.e. pooled, according to size, molecular, weight, etc. (see column 8, lines 12-65 and column 15, lines 8-24). The method is used to screen and detect for binding of a labeled target to any of the compounds extracted from the plant. The fractions containing the compounds each have a different location (ligand address) that corresponds to a tag having a known address identified by reference to a matrix on a solid support upon which the compounds are incorporated into, a well on a microtiter plate and a corresponding location on a membrane, i.e. plastic microtiter plate (see column 11, lines 16-64). The compound libraries are arrayed spatially in the matrix (see column 1, line 61 to column 2, line 26, column 3, lines 39-42, and column 4, lines 37-42). The compounds and target are contacted, incubated, washed with a buffer to remove unbound components, then detected for any complexes comprising the compound and labeled target protein, i.e. having a detectable moiety (see column 3, lines 62-67 and column 14, lines 19-24). Useful labels for the method and kit include biotin (see column 2, lines 14-17 and column 5, lines 11-23). Burmer discloses that the screening method finds use in pharmaceutical drug discovery and recovery for the development of lead compounds (see column 1).

Burmer differs from the instant invention in failing to disclose that the plant extract is from an herb, which is Carthamus tinctorius.

Baek et al. teach extracting and fractionating compounds from Carthamus tinctorius. Two biologically active flavonoid compounds have been isolated by repeat silica gel column chromatographies.

Verma et al. teach extracting and isolating compounds from Carthamus tinctorius. According to Verma et al., these biologically active compounds from Carthamus tinctorius have antithrombotic capacity (see page 740).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to screen an extract of the plant C. tinctorius as taught by Baek or Verma for compounds with biological activity, i.e. antithrombotic activity, using the method and kit of Burmer because Burmer specifically taught application of his simultaneous screening method for drug discovery of lead pharmacological compounds including those comprising small organic molecules such as those from plant extracts such as C. Tinctorius herbs as in the teaching of Baek or Verma.

5. Claims 18 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burmer (US 6,087,103) in view of Kutsuna et al. (Journal of the Pharmaceutical Society of Japan, November, 1988) (Abstract)).

Burmer has been discussed supra. Burmer differs from the instant invention in failing to teach that the protein target is a glycoprotein or a platelet membrane receptor protein.

Kutsuna et al. isolate, identify, and determine a biologically active compound from safflower Carthamus tinctorius. The compound is a platelet aggregation inhibitor which exhibits in vivo anti-thrombotic activity, and which inhibits glycoprotein (GPIIbIIIa) binding to serum proteins. The compound is induced by adenosine diphosphate, and is identified as adenosine.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the protein taught in the method of Burmer with glycoprotein or a platelet membrane receptor protein as taught by Kutsuna to screen an extract of plant for compounds having biological activity, i.e. platelet aggregation inhibition, because Burmer specifically taught application of his simultaneous screening method for drug discovery of lead pharmacological compounds including those comprising small organic molecules from plant extracts that are capable of platelet aggregation inhibition, affecting platelet membrane receptor glycoprotein IIb/IIIa as in the teaching of Kutsuna.

6. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burmer (US 6,087,103) in view of Baek et al. (Agricultural Chemistry and Biotechnology, April 1998 (Abstract)) or Verma et al. (Journal of Medicinal and Aromatic Plant Sciences, September 1997), as applied to claims 16, 29, and 30 above, and in further view of Kutsuna et al. (Journal of the Pharmaceutical Society of Japan, November, 1988) (Abstract)).

Burmer and Baek et al. or Verma et al. have been discussed supra. Burmer and Baek et al. or Verma et al. differ from the instant invention in failing to disclose that the recovered compound has a molecular weight of 268 gm/mole and is self-polymerizable.

Kutsuna et al. isolate, identify, and determine a biologically active compound from safflower Carthamus tinctorius. The compound is a platelet aggregation inhibitor which exhibits in vivo anti-thrombotic activity, and which inhibits glycoprotein (GPIIbIIIa)

binding to serum proteins. The compound is induced by adenosine diphosphate, and is identified as adenosine.

Kutsuna et al. is silent in teaching that the compound exhibiting platelet aggregation inhibition, has a molecular weight of 268 gm/mole and is self-polymerizable.

It is, however, maintained that inherent properties of an isolated active compound, i.e. molecular weight of 268 gm/mole and self-polymerizability, that has been identified in this case as adenosine, can be obtained using routine optimization procedures. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover optimum values of inherent properties by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). Accordingly, it would have been obvious for one of ordinary skill to have discovered the optimum values of inherent properties of isolated active compounds obtained in the method disclosed by Burmer from plants or herbs such as C. tinctorius as taught by Baek or Verma, having biological activity as identified by Kutsuna, by normal optimization procedures.

Response to Arguments

7. Applicant's arguments filed 7/18/02 have been fully considered but they are not persuasive.

A) Applicant argues that Burmer has no disclosure or suggestion of fractionating a crude plant extract to obtain fractions.

Contrary to Applicant's argument, Burmer teaches and suggests application of the claimed method to screen for compounds which includes a step of fractionation from plant extracts in column 8, lines 12-64. Specifically, Burmer discloses a method and kit to screen a plant extract for compounds, i.e. small organic molecules, that bind selectively to a target protein wherein a crude plant is fractionated to obtain fractions and pooled, according to size, molecular, weight, etc. The method is used to screen and detect for binding of a labeled target to any of the compounds extracted from the plant. The fractions containing the compounds each have a different location that corresponds to a tag having a known address identified by reference to a matrix on a solid support upon which the compounds are incorporated into. The compound libraries are arrayed spatially in the matrix.

B) Applicant argues that Burmer utilizes a different approach of a method from that set forth by the instant invention; that is the solid support having a multiplicity of fractions of plant extract is treated with a single labeled target, not a multiplicity of labeled targets, as described by Burmer.

Contrary to Applicant's argument, Burmer, indeed, teaches or suggests an embodiment comprising a method described by the claimed invention at column 1, line 61 to column 2, line 5 and column 8, lines 12-64. Specifically, Burmer discloses a method and kit to screen a plant extract for compounds, i.e. small organic molecules, that bind selectively to a labeled target protein wherein the compounds each have a different location that corresponds to a tag having a known address identified by

reference to a matrix on a solid support upon which the compounds are incorporated into.

C) Applicant argues that the combination of Burmer with Baek does not suggest the claimed invention because Baek only suggests that extracts of C. tinctorius may contain biologically active compounds, though not necessarily those obtained by Applicant.

In response to applicant's argument that the references fail to show certain features of applicant's invention, i.e., C. tinctorius may contain biologically active compounds, though not necessarily those obtained as recited by Applicant, it is noted that this feature is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

D) Applicant argues that the combination of Burmer with Verma does not suggest the claimed invention because there is no teaching in either Burmer or Verma as to how any screening should be conducted for this anti-thrombotic activity.
In response to applicant's argument that the references fail to show certain features of applicant's invention, i.e., how screening should be conducted for this anti-thrombotic activity, it is noted that this feature is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed.

Cir. 1993). Alternatively, screening for compounds as recited in the claimed invention is taught and suggested by Burmer including a step of fractionation from plant extracts in column 1, line 61 to column 2, line 5 and column 8, lines 12-64. Specifically, Burmer discloses a method and kit to screen a plant extract for compounds, i.e. small organic molecules, that bind selectively to a target protein wherein a crude plant is fractionated to obtain fractions and pooled, according to size, molecular, weight, etc. The method is used to screen and detect for binding of a labeled target to any of the compounds extracted from the plant. The fractions containing the compounds each have a different location that corresponds to a tag having a known address identified by reference to a matrix on a solid support upon which the compounds are incorporated into. The compound libraries are arrayed spatially in the matrix.

8. No claims are allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R Gabel whose telephone number is (703) 305-9297. The examiner can normally be reached on Monday-Thursday 6:00 AM to 3:30 PM and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gailene R. Gabel
April 5, 2003

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
04/08/03